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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,679	04/28/2006	Britta Hardy	31831	9819
7590 Martin D. Moynihan PRTSI, Inc. P.O. Box 16446 Arlington, VA 22215		07/12/2007	EXAMINER NIEBAUER, RONALD T	
			ART UNIT 1654	PAPER NUMBER
			MAIL DATE 07/12/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/577,679

Applicant(s)

HARDY ET AL.

Examiner

Ronald T. Niebauer

Art Unit

1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 36-69 is/are pending in the application.
- 4a) Of the above claim(s) 41-43, 45, 47-52, 55, 57, 59, 61 and 63-69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-40, 44, 46, 53, 54, 56, 58, 60 and 62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 2/20/07, 4/28/06.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Group I (claims 36-46,53-54,56-58,60-62,64,66-67) and the species of SEQ ID NO:10 in the reply filed on 4/27/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-35 have been cancelled.

Claims 41-43,45,47-52,55,57,59,61,63-69 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention/species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/27/07.

Regarding Markush type generic claims, section 803.02 of the MPEP states:

'Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable, the provisional election will be given effect and examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.'

Specifically, claims 41-43,45,57,61,64,66,67 are withdrawn as they read on non-elected species of a different SEQ ID.

### ***Specification***

The disclosure is objected to because of the following informalities:

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The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Specifically, page 31 (line 10), 55 (line 9) and figure 22 all contain an embedded hyperlink and/or other form of browser-executable code.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 37, 40, 53, 56, 60** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The scope of the claimed invention is not clear. It is not clear if claim 37 is drawn to a peptide consisting of the recited sequence; a peptide comprising the recited sequence; or a peptide comprising any portion of the recited sequence. Claim 37 is drawn to a peptide of a particular sequence, but since claim 40 recites that the peptide is no more than 50 amino acids claim 37 must be open to more than consisting of the recited sequence.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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**Claims 36-40,56,60** are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. For claims 36,38 and dependent claims the claim language is such that any portion of the recited sequence reads on the claims. Any naturally occurring protein which comprises, for example Tyr-Pro, reads on the claimed invention. For claim 37 and dependent claims the claim scope is unclear so the claim has also been interpreted broadly to include any portion of the recited sequences. Further, the specification (page 14 line 18) notes that the term peptide encompasses native peptides. Hence it is possible that the peptide is naturally occurring and has not been isolated or removed from a naturally occurring environment. The claimed subject matter therefore reads on a product of nature.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 36-40,46,53-54,56,58,60,62** are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Blaschuk et al. (US 6,638,911).

Briefly, claim 36,38 and dependent claims recites a peptide comprising an amino acid sequence selected from a particular group. Due to the claim language the claim encompasses peptides that comprise the full-length sequence of SEQ ID NO:10 or 6, or any portion of SEQ ID NO:10 or 6.

Briefly, claim 37 recites a peptide of a certain SEQ ID. This claim does not specify if the peptide comprises, includes, or consists of the particular SEQ ID nor does the specification. Hence, the broadest interpretation of the claims (see MPEP section 2111) for 'a peptide' would be any portion of the recited SEQ ID.

Blaschuk teach a peptide comprising the sequence HIDS (SEQ ID:405, claim 10) which is a peptide of a portion of SEQ ID NO:10 of the current invention. This peptide is less than 50 amino acids in length, can be cyclical (column 7 line 15), can be used in a pharmaceutical composition (column 7 line 59), and linked to a drug (column 7 line 47).

**Claim 44** is rejected under 35 U.S.C. 102(b) as being anticipated by Sakharov et al. (EP 1136082 A1 as cited in IDS).

Briefly, claim 44 recites a composition comprising peptides.

Sakharov teach peptides VW1 and VW2 which correspond to SEQ ID NO:2 and SEQ ID NO:12 of the current invention. Specifically, these peptides are taught in section 0028 and 0040. Section 0040 teaches that the sequences were identified from a phage library so these peptides were together in a composition of matter in the phage library.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**Claims 36-40,46,56,58,60,62** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,4 of copending Application No. 11411832. Although the conflicting claims are not identical, they are not patentably distinct from each other because SEQ ID NO:1 of Application No. 11411832 includes Arg-Arg which is in SEQ ID NO:10 of the current application. Due to the claim language the current claim encompasses peptides of any portion of SEQ ID NO:10. Claim 4 of Application No. 11411832 reads on pharmaceutical compositions. Although the current claim language is different the current claim is anticipated by the reference claim.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**Claims 36-40,46,56,58,60,62** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,4 of U.S. Patent No. 7,122,372. Although the conflicting claims are not identical, they are not patentably distinct from each other because SEQ ID NO:1 of U.S. Patent No. 7,122,372 includes Arg-Arg which is in SEQ ID NO:10 of the current application. Due to the claim language the current claim encompasses peptides of any portion of SEQ ID NO:10. Claim 4 of U.S. Patent No. 7,122,372 reads on pharmaceutical compositions. Although the current claim language is different the current claim is anticipated by the reference claim.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ronald T. Niebauer whose telephone number is 571-270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

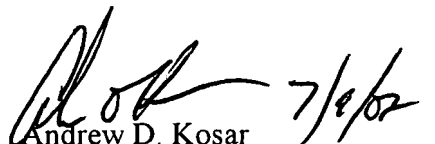
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

rtn

  
Andrew D. Kosar  
Patent Examiner, Art Unit 1654